

Clinical Laboratory Program

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CLINICAL LABORATORY LICENSURE
FREQUENTLY ASKED QUESTIONS ABOUT LICENSURE

How can a laboratory determine which license to apply for - limited or full.

Response: As defined in CIRCULAR LETTER DHCQ-1-93-333, the Department expanded its limited test category to include all tests classified by CLIA (Clinical Laboratory Improvement Amendments of 1988) as “moderate complexity”. If a laboratory performs only moderately complex tests then the application should be for a limited license; if a laboratory performs one or more highly complex tests then it must apply for a full license.

How long does it take to obtain a license?

Response: The first step required for licensure is the submission of a complete licensure packet to the Department. Once all paperwork is received, it takes 10-14 days for the CORI forms to be processed. Once the suitability review is complete a surveyor contacts the laboratory and sets up a mutually acceptable date for an on-site survey. Once the laboratory is found to be in complete compliance with all of the regulations a license is issued. Licenses are good for two (2) years. Changes in ownership require the new owners to apply for a new clinical laboratory license.

What are “exempt” tests?

Response: “Exempt” tests refers to tests performed in a physician office laboratory which are generally non-instrumental in nature and the results of which are determined by observation of a visual signal. These test are only used to determine if a physician office laboratory is exempt from licensure. If the laboratory is not exempt, then all tests performed by the laboratory must comply with the clinical laboratory regulations.

Erythrocyte sedimentation rate	Complete urinalysis with microscopy
Occult Blood (stool) tests	Sickle Cell Screening
Scotch Tape Prep for Pin Worm Ova	Wet Smears (e.g., trichomonas, yeast, KOH)
Pregnancy Test (qualitative)	Capillary Whole Blood Glucose
Capillary Whole Blood Cholesterol	Capillary Whole Blood Hemoglobin
Capillary Whole Blood Prothrombin Time (INR)	Capillary Whole Blood Hematocrit
Latex Slide Tests, qualitative (no dilution required)	Serological tests directly from swab
Throat culture, screening only (including bacitracin disc)	Urine culture, screening only

What are “simple” tests?

Response: Simple tests refers to tests performed in a physician office laboratory which may require a series of steps/reagent additions or instrumentation, and the results of which are generally determined by a visual signal. These tests are used to determine if a physician office laboratory requires a full or limited license. Based on the circular letter from 1993 this group of tests is now interpreted to be any CLIA moderately complex test.

What is the difference between a collection station and a satellite laboratory?

A **collection station** is a facility which is maintained at a separate physical location not on the grounds or premises of the main licensed laboratory or institution which performs the testing. **No** laboratory testing is allowed in a collection station. All collection stations must be approved prior to providing services. **Only independent laboratories, hospitals and clinics may open collection stations.**

A **satellite** laboratory is a physician office laboratory which is located off the premises of the primary or parent office of the group practice and is located in the secondary office of the same group practice; or a laboratory which is located off the premises of a state licensed hospital or clinic. **Only physician offices, hospitals and clinics may open satellite laboratories.**

What is the difference between an independent laboratory and a physician office laboratory?

A physician office laboratory is one which is maintained by more than two physicians exclusively in connection with the diagnosis and treatment of their own patients. All other laboratories are considered independent laboratories. The regulations apply equally to independent and physician office laboratories except for collection stations [independent laboratories] and satellite laboratories [physician office laboratories].

Are CLIA waived tests exempt from state regulations?

CLIA waived status does not apply to state laboratory licensure. All facilities that perform testing must comply with all of the regulations for all of the tests performed unless **the facility is exempt from licensure. Massachusetts does not exempt tests from the regulations; it exempts facilities.** Once it is determined that clinical laboratory licensure is required, all tests performed by the laboratory must meet all of the regulations.